K030951

JUN - 6 2003

Section 5

Contact: Stephen D. Smith

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 190 and 21 CFR par 807.92

Trade Name:	**TESCERAFLO**
Common Name:	Composite Restorative Material
Classification name:	Material, Tooth Shade, Resin
	Class II per 21 CFR 872.3690

Description of Applicant Device:
TESCERAFLO is a dual-cured (light/heat), moderately filled (60% by weight) low modulus flowable composite. It can be light cured by conventional means or processed in a dedicated curing device such as TESCERA ATL that employs heat and light in an oxygen-free environment. It is supplied in a syringe.

Intended uses of Applicant Device:
TESCERAFLO is a dual-cure (heat/light) composite designed to be used for direct or indirect restorations. Its physical properties are similar to the predicate device and uses are identical.

Predicate Devices: NTL-FLOW

Significant Performance Characteristics:

	NTL-FLOW	**TESCERAFLO**
Intended use	**Flowable composite**	**Flowable composite**
Chemical composite	**Dual-cured (light/heat) barium glass and silica filled (60%), dimethacrylate composite**	**Dual-cured (light/heat) barium glass and silica filled (60%), dimethacrylate composite**
Mechanical/Physical Properties	**Relatively low viscosity, syringable composite**	**Relatively low viscosity, syringable composite**

Side by side comparisons of TESCERAFLO to the predicate device NTL-FLOW clearly demonstrates that the applicant device is substantially equivalent to the legally marketed devices. TESCERAFLO was tested for biocompatibility and were found to be non-toxic.
It is concluded that the information supplied in this submission has proven the safety and efficacy of TESCERAFLO.

Stephen D. Smith
Manager Regulatory Affairs
Telephone: 847 534-6146
Fax: 847-534-6396

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2003

Kathy Joung, Ph.D.
Director of Quality Systems
Bisco, Incorporated
1100 West Irving Park Road
Schaumburg, Illinois 60193

Re: K030951
Trade/Device Name: TESCERAFLO™
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: March 24, 2003
Received: March 26, 2003

Dear Dr. Joung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030951

Device Name: TESCERAFLO

Indications For Use:

1. Esthetic restorative material for Class III, IV, and V.
2. Conservative Class I and Class II not involving opposing occlusal contact for direct or indirect use.
3. Direct Esthetic veneer restorative for masking stains and developmental anomalies.
4. Pit and fissure sealant.
5. Core buildup material to replace missing tooth structure.
6. Direct cement/luting agent and dental liner.
7. Indirect cement for use with reinforcement materials to fabricate crowns and bridges.
8. Composite/porcelain repair material.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kim Mealey for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030951

(Optional Format 3-10-98)